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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,584	12/20/2001	Michael V. Chobotov	24641-1120	4975

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/14/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,584

Applicant(s)

CHOBOTOV ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 26-29, 36 and 38-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-25, 30-35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-37 in Paper No. 12 is acknowledged. This election, as filed on 5/19/03 is incomplete for omitting to elect a subspecies, as required on page 3 of the Election/Restriction mailed 5/2/03. A telephone call was made to Mr. Craig P. Wong, wherein an election of subspecies (1)(a), claims 1-6, 11-25 and 30-37 was made without traverse on 7/11/03.
2. The examiner has additionally withdrawn claim 36 for being drawn to the non-elected subspecies (1)(b). The claims withdrawn from consideration are 7-10, 26-29, 36 and 38-61. The claims being considered for further examination on the merits are 1-6, 11-25, 30-35 and 37.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the flap formed of a layer that is secured to another layer (claims 11 and 30) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

✓ A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: the blanks under “Related Applications” on page 1 must be filled in with the most up-to-date information, including filing and patent dates and numbers. On page 4, line 5, the sentence ending with “expandable” is incomplete.

Appropriate correction is required.

Claim Objections

5. Claims 20, 23, 34 and 35 are objected to because of the following informalities:

- ✓ a. In claims 20 and 34, line 2, “an” before “connector” should be changed to --a--.
- ✓ b. In claim 23, line 2, “comprisesnickel” should be changed to --comprises nickel--.
- ✓ c. In claim 35, line 1, --a-- should be inserted after “between”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6, 11, 18, 19, 21, 25, 30 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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✓ 7. Claims 2, 11, 21 and 30 are indefinite because it is not the *flap* of flexible material that is formed of a layer that is secured to itself or to another layer. It is the *loop* that is formed by securing the flap to itself or another layer.

✓ 8. Regarding claims 19 and 34, the word "means" is preceded by the word(s) "joining" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Examiner suggests changing "joining means" to --means for joining--.

✓ 9. Claims 6 and 25 are indefinite because the Markush listing of elements is not written correctly. On line 2, "comprising" should be changed to --consisting of--.

✓ 10. Claim 18 is indefinite because it is not commensurate in scope with claim 17, on which it depends. What about the portion of the expandable stent?

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3-5, 13-20, 22-24 and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. (USPN 6,149,681).

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Houser et al. discloses an implantable vascular graft with all the elements of claims 1, 19, 20, 34 and 35. See Figures 8 and 9 and column 8, lines 33-51 for an endovascular graft (76) comprising a flexible material portion (80) and a transversely oriented member/connector member (90) secured to the flexible material portion with a joint that includes at least one flap (92) of the flexible material folded back and secured to (at 94) about the transversely oriented member/connector member (90). The graft configuration shown in Figure 9 provides the flap with a configuration that is inherently capable of transferring tensile force on the transversely oriented member/connector member into a shear component of force on the flap and flexible material portion. The method of forming a joint disclosed in column 8, lines 33-51 of fixing a flap (92) of the flexible material portion (80) about at least a portion of the connector member (90) provides a configuration that is inherently capable of transferring the tensile force on the connector member into a shear force on the fixed portion of the flap.

Claims 3, 4, 22 and 23, see column 7, lines 19-20 and 50-58 for transversely oriented member/connector member comprises a material, nickel titanium, having a higher strength relative to the strength of the flexible material.

Claims 5 and 24, see column 8, lines 47-49 for securing the flap by bonding with an adhesive to the flexible material of the graft or section thereof.

Claims 13, 14, 32 and 33, see Figure 8 and column 8, lines 39-51 for the joint comprising a plurality of flaps, one flap around each of the top and bottom of the rectangular transversely oriented member/connector member (90) folded back and secured to form loop portions about the transversely oriented member/connector member.

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Claims 15-18, see abstract, column 7, lines 20-22 and column 8, lines 7-8 for transversely oriented member limitations.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 6, 25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Edwin et al. (USPN 6,245,099).

Houser et al. discloses an implantable vascular graft with all the elements of claims 1, 20 and 35, but is silent to the adhesive being selected from the group consisting of FEP and PFA, as required by claims 6, 25 and 37 and of the flexible material portion comprising ePTFE, as also required by claim 37. Edwin et al. teaches a graft wherein FEP is introduced between layers of ePTFE in order to selectively bond the layers together. See column 8, lines 40-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to make the flexible material portion of Houser et al. from the material well known in the vascular graft art, ePTFE, and to use FEP as the adhesive in Houser et al. to secure the flap to flexible material because it is well known in the art to effectively bond ePTFE to ePTFE. This will prevent the flap from separating from the flexible material during use.

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15. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al.

Houser et al. discloses an implantable vascular graft with all the elements of claims 1 and 20, but is silent to the at least one flap being specifically about 1 to 25 square millimeters, as required by claims 12 and 31. In Figure 8 of Houser et al., it is clear that the length of the flap (92) corresponds to the length of the top of the transversely oriented member/connector member around which the loop is formed. Because the length of top of the transversely oriented member/connector member determines the circumference of the vascular graft formed, variation in the length will provide grafts of different diameters made for different size vessels. A graft having a small diameter will therefore have a small flap area. Because the size of the graft will depend on the needs of the individual patient, it is obvious that the flap area required by claims 12 and 31 will be met by the implantable vascular graft of Houser et al.

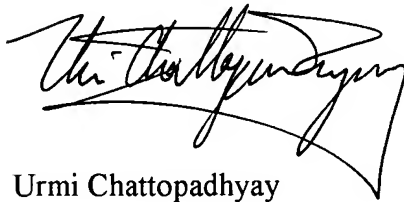
Allowable Subject Matter

16. Claims 2, 11, 21 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner

uc

August 8, 2003